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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/699,885 | 11/04/2003 | C. Edgar Cook | 244697us77cont | 3486 |
| 22850 | 7590 | 04/08/2004 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | BADIO, BARBARA P | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1616 | | |

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-----------------|-------------------------|--------------|-------------|
| Application No. | 10/699,885 | Applicant(s) | COOK ET AL. |
| Examiner | Barbara P. Badio, Ph.D. | Art Unit | 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 44-84 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
5) Claim(s) ____ is/are allowed.
6) Claim(s) 44-84 is/are rejected.
7) Claim(s) ____ is/are objected to.
8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 11/04/03; 3/22/04.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

First Office Action on the Merits

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 52-67, 83 and 84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite compounds of formula (I) wherein R⁴ is C₁₀ alkyl. However, the subgenus of compounds recited by the instant claims was not described in the present and/or parent specification. The addition of specific compounds after a broader original disclosure constitutes new matter because said subject matter was not described in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention (see MPEP § 706.03(o)).

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis

added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 45-51 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 of prior U.S. Patent No. 6,670,352. This is a double patenting rejection.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 68-84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 17 of U.S. Patent No. 6,670,352. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass a process of making 7 α ,11 β -

dimethyl-17 β [(trans-4-(n-butyl)cyclohexyl)carbonyl]oxy]estr-4-en-one. The present application differs from the patent by reciting a broader genus of compounds made. However, it would have been obvious to one of ordinary skill in the art to utilize the process of the present application in the production of 7 α ,11 β -dimethyl-17 β [(trans-4-(n-butyl)cyclohexyl)carbonyl]oxy]estr-4-en-one because the genus of compounds recited by the instant claim encompass the above-mentioned compound (see especially claim 82 of the present application).

7. Claims 44-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5-14 and 19-26 of U.S. Patent No. 6,369,047. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass 7 α ,11 β -dimethyl-17 β [(trans-4-(n-butyl)cyclohexyl)carbonyl]oxy]estr-4-en-one. The patent differs from the present application by reciting a broader genus of compounds. However, the compound of the instant application would be obvious to the skilled artisan because the cited patent teaches the instantly claimed compound, i.e., 7 α ,11 β -dimethyl-17 β [(trans-4-(n-butyl)cyclohexyl)carbonyl]oxy]estr-4-en-one (see claim 26, lines 27-28 of the above-cited patent).

8. Claims 44-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-14 and 19-25 of U.S. Patent No. 5,952,319. Although the conflicting claims are not identical, they are not

patentably distinct from each other because they both encompass $7\alpha,11\beta$ -dimethyl- 17β [(*trans*-4-(*n*-butyl)cyclohexyl)carbonyl]oxy]estr-4-en-one. The patent differs from the present application by reciting a broader genus of compounds. However, the compound of the instant application would be obvious to the skilled artisan because the cited patent teaches the instantly claimed compound, i.e., $7\alpha,11\beta$ -dimethyl- 17β [(*trans*-4-(*n*-butyl)cyclohexyl)carbonyl]oxy]estr-4-en-one (see claim 3, lines 20-21 of the above-cited patent).

Telephone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Radio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio
Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
April 6, 2004